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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/449,854	11/26/1999	Maria Grazia Pau	4240US	6774

24247 7590 01/11/2006

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/449,854

**Applicant(s)**

PAU, MARIA GRAZIA

**Examiner**

Myron G. Hill

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-16,25,27-29,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-16,25,27-29,37 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/11/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This paper is in response to amendment filed 11 October 2005.

Claims 1-3, 5-16, 25, 27-29, 37, and 38 are under consideration.

Claims 30-34 are canceled as of the amendment filed 4 October 2001, and are not withdrawn as indicated in the current listing of claims.

#### ***Information Disclosure Statement***

A signed and initialed copy of the IDS paper filed 11 October 2005 is enclosed.

#### ***Rejections Withdrawn***

##### ***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5-16, 25, 27-29, and 37-38 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what the metes and bounds of "functional derivative", "analogue", "derived", and "fragment" are.

Applicant has amended the claims and the rejection is withdrawn.

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Claims 11-3, 5-16, 25, 27-29, and 37-38 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of growing influenza virus in PER.C6 cell, does not reasonably provide enablement for "functional derivative", "analogue", "derived", and "fragment" of E1 and E2A or other viruses and other cell types. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant has amended the claims and the rejection is withdrawn.

Claims 17 and 37 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim is drawn to a range of viruses to be used in the method of claim 1 and purification by chromatography.

Applicant has amended the claims and the rejection is withdrawn.

### ***Claim Rejections - 35 USC § 102***

Claims 1-3, 5, 6, 14, 15, 17, 25, and 38 were rejected under 35 U.S.C. 102(b) as being anticipated by Manservigi *et al.*

Applicant has amended the claims and the rejection is withdrawn.

Claims 25-29 were rejected under 35 U.S.C. 102(b) as being anticipated by WO97/00326.

Applicant has amended the claims and the rejection is withdrawn.

Claims 1-3, 5, 6, 14, and 15 were rejected under 35 U.S.C. 102(b) as being anticipated by Massie *et al.* (US 5518913).

Applicant has amended the claims and the rejection is withdrawn.

Claims 1-3, 5-16, 25, 27-29, and 37-38 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6855544.

The rejection is withdrawn as the specific invention claimed in the patent is not supported by the provisional application and thus is not prior art.

### ***Claim Rejections - 35 USC § 112***

Claim 13 was rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the said claims. The claim requires a specific deposited cell. Deposit of the cell would satisfy the enablement requirements of 35 U.S.C. 112.

Claim 27 has been amended to recite the same cell line

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The declaration supplied is correct in form. It is noted that it is not made by the assignee of record. The declaration is from "Crucell" and the assignment on record is "Introgene".

***New Rejections***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-17, 25, 27-29, and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6855544.

Applicant's response argues that the patent (in the 102 (e) rejection) does not teach the limitation "infecting cells with influenza virus" and thus does not anticipate the claim.

Applicant's arguments have been fully considered and not found persuasive.

The claims are not limited to influenza virus infections but clearly include production of influenza viral proteins, see claim 1, lines 1 and 2 as amended.

The claims of the patent interfere with the pending claims because they claim/recite the same invention of producing influenza viral proteins in a particular cell type. The patent is not available as prior art on the now claimed invention because the

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production of influenza proteins is not supported in the provisional application. The date of the provisional is available as prior art under 35 USC 103. The patent claims expression of influenza virus proteins, a declaration under 1.131 cannot be used to swear behind the invention because the patent claims the same as the pending claims.

The provisional application of Hateboer *et al.* teach the expression of proteins in human retinoblast cells including PER.C6 and a cell line that is able to express human proteins well because it glycosylates the protein in a human like way as well as the advantage of the cell that it grows well and is immortalized by the Adenovirus E1 gene (see pages 4 and 5).

The provisional does not teach influenza.

One of ordinary skill in the art at the time of invention would have been motivated use the cells of Hateboer *et al.* for the expression of influenza viral proteins with the expectation of success because the proteins would be properly glycosylated because they are expressed in human cells. One of skill in the art would have the expectation of success because the of the benefits of human glycosylation as taught by Hateboer *et al.* and the high level of skill in the art of protein expression.

Thus, it would be prima facie obvious to express influenza proteins by the method of Hateboer *et al.* with the expectation of success knowing that the cell is very good for expressing heterologous protein in a human cell.

### ***Conclusion***


No claim is allowed.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Myron G. Hill  
Patent Examiner  
18 October 2005

  
JAMES HOUSEL 11/9/06  
SENIOR PATENT EXAMINER  
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